Remarks

Introduction

Claims 1-7, 11, 12, 15, 17-20, 22, 25-41, and 85-93 were pending, and claims 86-93 have been withdrawn from consideration. By way of this response, claims 1, 2, 27, 28, 30, 38, 85, and 88 have been amended, and claims 5-7, 25, 26, 29, 31-37, and 39-41 have been cancelled without prejudice. Support for the amendments to the claims may be found in the specification as originally filed, and care has been taken to avoid adding new matter. Accordingly, claims 1-4, 11, 12, 15, 17-20, 22, 27, 28, 30, 38, and 85-93 are currently pending.

Claim 1 has been amended to include the subject matter of claims 6, 26, 29, and 37, and claims 6, 26, 29, and 37 have been cancelled. The other pending claims have been amended to read more clearly, including in view of the amendments to claim 1.

Election/Restriction

The Office Action indicates that restriction to one invention is required under 35 U.S.C. § 121. The Examiner has indicated that the invention of Group I (claims 1-7, 11-12, 15, 17-20, 22, 25-41, and 85) and the invention of Group II (claims 86-93) are independent and distinct because the inventions are allegedly unrelated since the Examiner believes the inventions are not capable of use together and have different modes of operation, different functions, or different effects. The Examiner contends that the kits of Group I and Group II are patentably distinct because the kit of Group II includes a plurality of reagents including 25-OH-D coupled to a solid phase, and these reagents are not found in the kit of Group I.

Applicant acknowledges that claims 86-93 have been withdrawn from consideration. However, Applicant traverses the restriction requirement, and requests rejoinder of the claims.

Among other things, Applicant submits that the subject matter of claim 86, and the claims dependent therefrom, was present in the claims of Group I, as identified by the Examiner. For

example, the subject matter of claim 86 includes some of the subject matter of cancelled claims 6 and 29. Thus, Applicant submits that the present claims should not be subject to restriction at least because the Examiner has indicated that claims 6 and 29 are claims of Group I.

In addition, claim 1 has been amended to include subject matter from claims 6, 26, 29, and 37. Applicant traverses the restriction requirement, especially in view of the amendments to claim 1, and submits that there would be no burden on the Examiner to search or examine the present claims (e.g., the claims of Groups I and II if they were grouped together). As acknowledged in the Office Action, both groups of claims are drawn to kits for determining an amount of vitamin D in a sample. The present kits comprise a releasing composition that comprises a cyclodextrin, a salicylate, and a base. In addition, claim 1 has been amended to identify additional elements in the kit, which can be provided in a plurality of reagents. Applicant submits that simply not reciting the same elements in the claims is not sufficient to support the Examiner's contention that the kits have different modes of operation and are not capable of use together. Applicant submits that the kits of the present claims, and claims 1 and 86 in particular, can be used together and do not necessarily have different modes of operation.

Therefore, applicant respectfully submits that the restriction of Group I and Group II is improper, especially in view of the amendments to claim 1, which include subject matter from other claims of Group I, and requests the Examiner to rejoin the claims of Group I and Group II, and that examination be conducted on all of the present claims (i.e., claims 1-4, 11, 12, 15, 17-20, 22, 27, 28, 30, 38, and 85-93).

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-7, 11-12, 15, 17-20, 22, 25-41, and 85 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite.

Claim 1 has been amended as set forth above, and claims 5, 6, and 7 have been cancelled. Claim 1 has been amended to identify additional reagents of the kit, such as 25-hydroxy vitamin D

coupled to a solid phase; vitamin D binding protein; and a vitamin D binding protein antibody coupled to a label present in an amount that produces a detectable signal with 25-hydroxy vitamin D is present in the sample.

Applicant submits that the present claims are definite, and that the present claims clearly indicate that there are at least two different forms of 25-hydroxy vitamin D mentioned (e.g., 25-hydroxy vitamin D that is present in a sample, and 25-hydroxy vitamin D coupled to a solid phase). The 25-hydroxy vitamin D coupled to a solid phase is positively recited as an element of the presently claimed kits. The 25-hydroxy vitamin D present in a sample, at least initially, is not a component of the kit. However, it may be understood that the 25-hydroxy vitamin D may become a component of the kit during the assay procedure.

In view of the above, Applicant submits that the claims satisfy the requirements of 35 U.S.C. § 112, second paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1-6, 11, 12, 15, 17-20, 22, 23, and 41 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,121,975 (Ullman et al.) in view of U.S. Patent No. 4,444,789 (Foster et al.). Claims 7, 25-27, and 38-40 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ullman et al. in view of Foster et al. and further in view of U.S. Patent No. 5,064,770 (DeLuca et al.). Claims 28-40 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ullman et al. in view of Foster et al. and further in view of DeLuca et al., and further in view of U.S. Patent No. 5,770,176 (Nargessi et al.).

Applicant does not concede with the rejections or reasoning proposed by the Examiner. However, Applicant submits that the rejections are moot in view of the amendments to the claims. Applicant traverses the rejections as they relate to the present claims, and submits that

the cited references, taken alone or in any combination, do not disclose, teach, or suggest all of the elements recited in the present claims.

Applicant submits that the cited references, taken alone or in any combination, do not disclose, teach, or suggest the present invention. For example, the cited references, taken alone or in any combination, do not disclose, teach, or even suggest, a kit which includes 25-hydroxy vitamin D coupled to a solid phase in combination with the other elements of the present claims. As recited in claim 1, the kit also comprises a releasing composition which comprises specific amounts of a cyclodextrin, a sodium salicylate, and NaOH, a vitamin D binding protein, and a vitamin D binding protein antibody (anti-DBP antibody) coupled to a label that can produce a detectable signal. As recited in claim 86, the kit also comprises a composition which includes a cyclodextrin, a salicylate, and an aqueous base component in a certain amount, and a label provided in an amount to produce a detectable signal.

Ullman et al. discloses a composition in an assay for thyroxine. As understood by persons of ordinary skill in the art, thyroxine and 25-OH-D are structurally and functionally different and distinct, one from the other. Thus, Applicant submits that a person of ordinary skill in the art studying kits and methods of detecting 25-OH-D in a sample would not look at a disclosure related to assays for thyroxine.

In addition, Applicant submits that the kit of the present claims includes 25-OH-D coupled to a solid phase, among other things. 25-OH-D is used in a competitive manner to compete with 25-OH-D present in a sample. Ullman does not disclose, teach, or even suggest including 25-OH-D in the composition used in the thyroxine assay. Applicant submits that Ullman actually teaches away from including 25-OH-D, let alone 25-OH-D coupled to a solid phase, in the thyroxine assay composition since 25-OH-D would not competitively interact with thyroxine. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)).

Ullman et al. also does not disclose, teach, or even suggest a kit comprising a label provided in an amount to produce a detectable signal when 25-OH-D is present in the sample being tested, as recited in the present claims. Furthermore, Ullman et al. does not disclose, teach, or even suggest a kit comprising a vitamin D binding protein, and a vitamin D binding protein antibody coupled to a label, as recited in claim 1.

Foster et al. discloses a solid phase support for immobilizing reactants of an immunoreaction and devices that include such a support.

Foster et al., the secondary reference, does not make up for the deficiencies of Ullman et al. For example, Foster et al. does not disclose, teach, or even suggest a kit which comprises 25-OH-D coupled to a solid phase, as recited in the present claims. In addition, Foster et al., does not disclose, teach, or even suggest a label in an amount that produces a detectable signal when 25-OH-D is present in a sample being tested, as recited in the present claims. Furthermore, Foster et al. does not disclose, teach, or even suggest a kit which comprises a vitamin D binding protein and a vitamin D binding protein antibody, as recited in claim 1, let alone, the combinations of these elements as arranged in the present claims.

Applicant submits that since neither Ullman et al. nor Foster et al. individually disclose, teach, or suggest each and every element of the present claims, the combination of Ullman et al. and Foster et al. does not disclose, teach, or even suggest the present invention.

Applicant submits that since claim 1 and claim 86 are patentable over the combination of Ullman et al. and Foster et al., the present claims are also patentable over the combinations of Ullman et al., Foster et al., and DeLuca et al.; and Ullman et al., Foster et al., DeLuca et al., and Nargessi et al. Applicant submits that the additional references fail to make up for the deficiencies of Ullman et al. and Foster et al., and therefore, these additional combinations of references fail to disclose, teach, or even suggest all of the elements of the present claims.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present kits including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In view of the above, Applicant submits that the present claims, that is claims 1-4, 11, 12, 15, 17-20, 22, 27, 28, 30, 38, and 85-93, are unobvious from and patentable over the prior art, including Ullman et al., Foster et al., DeLuca et al., and Nargessi et al., taken alone or in any combination under 35 U.S.C. § 103.

Conclusion

In view of the above, Applicant has shown that the present claims are directed to a single invention, satisfy the requirements of 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-4, 11, 12, 15, 17-20, 22, 27, 28, 30, 38, and 85-93 are allowable. Applicant requests the Examiner to pass the above-identified application to issuance at an early date.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

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